P29301.A09

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Ulrike SCHULZ et al.

Confirmation No.: 2144
Group Art Unit: 1619

Serial No. : 10/574,231

Examiner: Lea, Christopher Raymond

I. A. Filed : March 10, 2005

For : TRANSPARENT COSMETIC OR DERMATOLOGICAL FORMULATION

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Commissioner for Patents
U.S. Patent and Trademark Office
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Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

This Appeal is from the Examiner's Final Rejection of claims 34-57 set forth in the Final Office Action mailed from the U.S. Patent and Trademark Office on August 26, 2009.

A Notice of Appeal in response to the August 26, 2009 Final Office Action was filed on December 28, 2009. A request for a one-month extension of time is being filed concurrently herewith.

The requisite fee under 37 C.F.R. § 41.20(b)(2) for filing this Appeal Brief and the fee for a one-month extension of time are being paid concurrently herewith. The Patent and Trademark Office is hereby authorized to charge any additional fees that may be deemed necessary for maintaining the pendency of this application, including any appeal or extension of time fees that may be deemed necessary, to Deposit Account No. 19-0089.

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I. REAL PARTY IN INTEREST

The real party in interest in this appeal is Beiersdorf AG of Hamburg, Germany. The corresponding assignment was recorded in the U.S. Patent and Trademark Office on August 31, 2006 at REEL 018243, FRAME 0908.

II. RELATED APPEALS AND INTERFERENCES

Appellants, Appellants' representative or the Assignee are not aware of any prior and pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

The status of the claims is as follows:

Claims 34-57 are pending in this application.

Claims 1-33 are cancelled.

Each of claims 34-57 is indicated as rejected in the Final Office Action mailed August 26, 2009.

The rejection of each of claims 34-57 is under appeal. Claims 34-57 involved in the appeal are reproduced in the Claims Appendix attached hereto.

IV. STATUS OF AMENDMENTS

An Amendment was filed subsequent to the August 26, 2009 Final Office Action on October 23, 2009. According to the Advisory Action mailed November 4, 2009 the Amendment has been entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Claim 34

Independent claim 34 is drawn to a cosmetic or dermatological formulation which is transparent and comprises (a) at least one antiperspirant active ingredient, (b) mandelic acid and (c) water. Components (a), (b) and (c) are present in ratios which result in gelling.

See, e.g., page 9, lines 12-14 and 20-27 and page 10, lines 3-7 of the present specification.

B. Claim 49

Independent claim 49 is drawn to a cosmetic or dermatological antiperspirant formulation which is free from zirconium containing antiperspirant active ingredients and transparent. The formulation comprises (a) an antiperspirant active ingredient which comprises one or more aluminum salts, (b) at least one α-hydroxycarboxylic acid and (c) water. Components (a), (b) and (c) are present in ratios which result in gelling.

See, e.g., page 9, lines 12-14 and 20-27 and page 10, lines 3-5 of the present specification.

C. Claim 55

Independent claim 55 is drawn to a cosmetic or dermatological antiperspirant formulation which is transparent and suitable for application to human skin. The formulation comprises (a) from 1% to 20% by weight of an antiperspirant active ingredient which comprises one or both of an aluminum salt and an aluminum zirconium salt, (b) from 0.1% to 8% by weight of mandelic acid and (c) water. Components (a), (b) and (c) are present in ratios which result in gelling.

See, e.g., page 9, lines 12-14 and 20-27 and page 10, lines 3-10, 14-21 and 24-25 of the present specification.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The broad issues under consideration are:

1. Whether claims 34-49, 52 and 55-57 are properly rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rubino, U.S. Patent No. 3,991,176 (hereafter "RUBINO") in view of Gross, U.S. Patent No. 7,189,406 (hereafter "GROSS") and Bhakoo et al., US 2003/0059396 A1 (hereafter "BHAKOO"), as allegedly evidenced by Hei et al., U.S. Patent No. 6,593,283 (hereafter "HEI"), and in particular, whether the disclosures of RUBINO, GROSS and BHAKOO are sufficient to establish a *prima facie* case of obviousness of the subject matter of claims 34-49, 52 and 55-57.

2. Whether claims 34-57 are properly rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Guskey et al., U.S. Patent No. 5,776,494 (hereafter "GUSKEY"), and in particular, whether the disclosure of GUSKEY is sufficient to establish a *prima facie* case of obviousness of the subject matter of claims 34-57.

Appellants note that according to the November 4, 2009 Advisory Action the following rejections which are set forth in the August 26, 2009 Final Office Action have been overcome by the Amendment filed October 23, 2009:

The rejection of claims 42, 43 and 45 under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The rejection of claims 49-51, 53 and 54 under 35 U.S.C. § 102(b) as allegedly being anticipated by RUBINO.

The Advisory Action also mentions a (withdrawn) rejection over RUBINO alone under 35 U.S.C. § 103(a). However, a corresponding rejection is not set forth in the August 26, 2009 Final Office Action.

Appellants further point out that the provisional rejections on the ground of nonstatutory obviousness-type double patenting based on co-pending application Nos. 10/574,219, 10/574,230 and 11/586,585 also set forth in the August 26, 2009 Final Office Action are not presented for review. Appellants will decide whether the submission of one or more terminal disclaimers is appropriate once allowable subject matter has been indicated in the instant application and in the co-pending applications.

VII. ARGUMENTS

A. Citation of Authority

Obviousness

The appropriate starting point for a determination of obviousness is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 U.S.P.Q. 459, 466 (1966):

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

The test of obviousness *vel non* is statutory and requires a comparison of the claimed subject matter as a whole with the prior art to which the subject matter pertains. *In re Brouwer*, 77 F.3d, 422, 37 U.S.P.Q. 2d 1663 (Fed. Cir. 1996); *In re Ochiai*, 71 F.3d 1565, 37 U.S.P.Q. 2d 1127 (Fed. Cir. 1995).

Often, it will be necessary to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. This analysis should be made explicit. There must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-1741. "A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be

important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id*, at 1741.

"If the Examiner fails to establish a *prima facie* case, the rejection is improper and will be overturned." *In re Rijckaert*, 9 F.3d, 1532, 28 U.S.P.Q.2d, 1956 (Fed. Cir. 1993), citing *In re Fine*, 837 F.2d 1071, 1074,5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

B. Claims 34-49, 52 and 55-57 Are Not Properly Rejected Under 35 U.S.C. 103(a) As Being Unpatentable Over RUBINO In View Of GROSS And BHAKOO

1. Summary of Rejection

The rejection asserts that RUBINO "teaches, as a whole, aluminum/zirconium antiperspirant compositions that contain hydroxycarboxylic acids". The rejection concedes that RUBINO does not use mandelic acid as the α-hydroxycarboxylic acid in the aluminium-zirconium antiperspirant complexes disclosed therein but essentially alleges that GROSS renders the use of mandelic acid in the complexes of RUBINO obvious to one of ordinary skill in the art. Alternatively, the rejection asserts that it would have been obvious to include mandelic acid in the compositions of RUBINO because BHAKOO allegedly teaches that malodor is the result of microorganisms and that generally deodorants work through an antimicrobial ability to decrease the population of microorganisms and because HEI allegedly teaches that mandelic acid possesses antimicrobial properties.

2. Traverse

a. Independent claims 34 and 55

Appellants point out that, independent claims 34 and 55 both recite, *inter alia*, the presence of mandelic acid in the cosmetic or dermatological formulations claimed therein. While RUBINO discloses several hydroxycarboxylic acids for use in the antiperspirant complexes taught therein, the list of exemplary acids (a total of 12 acids) does not include mandelic acid, and neither does this list include any aromatic ring containing acid (see col. 4, lines 23-26 of RUBINO). In other words, all of the specific acids mentioned by RUBINO are non-aromatic acids, thereby clearly failing to prompt one of ordinary skill in the art to consider an araliphatic acid such as mandelic acid for use in the complexes described therein.

Appellants submit that GROSS is unable to cure the noted deficiencies of RUBINO for several reasons.

First, there is no motivation for one of ordinary skill in the art to combine the teachings of RUBINO and GROSS. Specifically, according to col. 1, lines 17-20 of RUBINO the invention disclosed therein "is directed to water soluble complexes of zirconium which have a sufficiently high pH to be acceptable in anti-perspirant formulations for application to the human axilla".

In comparison the invention of GROSS "relates to dermatological compositions and methods, and more particularly to compositions and methods for use by consumers for the topical treatment of skin aging, acne, etc. and for the improvement of skin appearance" (col. 1, lines 6-10 of GROSS).

It is not seen that someone who wishes to improve or at least modify the (antiperspirant) formulations of RUBINO (which are to be applied to the human axilla) would expect to find any helpful information in this regard in a document which is not at all concerned with antiperspirant compositions (let alone with water-soluble complexes of zirconium) but with a completely different field of cosmetics, i.e., the treatment of skin aging, acne, etc., and the improvement in skin appearance. In other words, it is not seen that anyone would be interested in providing an antiperspirant composition which can also treat aging of the skin or acne of the armpit or improve the appearance of the skin of the armpit.

Appellants note that the Examiner "believes that applicant has underestimated the human vanity and the extremes to which people go in the pursuit of beauty" and states that GROSS was cited "mainly to show that mandelic acid is an α-hydroxycarboxylic acid which is suitable for topical application to human skin and only secondarily that it provides improvements in skin-appearance". Page 13, end of last paragraph of the August 26, 2009 Final Office Action.

In this regard, Appellants submit that the question here is not whether certain individuals would be vain enough to worry about the appearance of their armpits, but whether one of ordinary skill in the art of cosmetic compositions would be prompted to include mandelic acid in the zirconium complex containing antiperspirant compositions of RUBINO merely because mandelic acid is mentioned in GROSS in connection with a method for improving the appearance of the skin and in a completely different context (see below).

Secondly, the function of the acid in the compositions taught by GROSS is completely different from the function of the hydroxycarboxylic acid for use in the antiperspirant complexes of RUBINO. In this regard, it is pointed out that, GROSS states in col. 2, lines 43-56 thereof (emphasis added):

> The present invention is directed to a two-step acid peel for the skin gentle enough for use by the consumer at home but capable of providing an improvement in the skin comparable to results previously obtainable only by professionals using higher concentrations of acid. This method comprises the steps of applying to the skin a first composition comprising a skin renewing acid component in a cosmetically acceptable vehicle, wherein the pH of the first composition is between about 2.5 and about 4, and neutralizing the first composition by applying to the skin a second composition comprising an alkaline agent and from about 0.1 to about 10% of at least one surfactant/emulsifying agent in a cosmetically acceptable vehicle, wherein the pH of the second composition is greater than about 7.

Accordingly, GROSS teaches that mandelic acid must not be kept on the skin for extended periods of time but is used only in the first step of a two-step acid peel for the skin wherein in a first step a composition comprising a skin renewing acid component (for example and among many other acids, mandelic acid) is employed followed, in a second step, by the application of a neutralizing composition which comprises an alkaline agent (which is used to neutralize the renewing acid component).

Thirdly, in contrast to the renewing acid component of GROSS the hydroxycarboxylic acid of RUBINO is not employed as such but in the form of a complex with specific metal compounds. In particular, in col. 2, lines 3-15 thereof RUBINO states:

> According to the present invention, it has been found that effective anti-perspirant compositions may be achieved by forming a water soluble complex which comprises a combination of a basic aluminum compound, a zirconium compound selected from zirconium oxy salts, zirconium hydroxy salts and mixtures thereof, and a hydroxy carboxylic compound selected from non-toxic salts of hydroxy carboxylic acids, non-toxic salts of aluminum chelates of hydroxy

carboxylic acids, codried mixtures of aluminum hydroxide with non-toxic salts of aluminum chelates of hydroxy carboxylic acids, and mixtures thereof.

Lastly, regarding the acid for use in the first step of the peeling method taught therein GROSS states in col. 3, lines 46-67 (a part of which is also relied upon by the Examiner; emphasis added):

> The skin-renewal stimulating acid can be a hydrophilic acid or other acid-equivalent electronegatively hydrophilic organic compound selected from the group consisting of hydroxy carboxylic acids, keto acids, hydroxybenzoic acids and related compounds. Preferred compounds have a relatively lower molecular weight as higher molecular weight compounds tend to be hydrophobic and may have too little activity. Since the smallest molecules such as formic acid, are unduly aggressive, a preferred molecular weight range is from about 50 to about 250.
>
> Preferred acids include alpha-hydroxy acids, salicylic acid and other beta hydroxy acids, and combination thereof. Preferably the composition of Step 1 includes at least one alpha hydroxy acid selected from the group consisting of glycolic acid, lactic acid, malic acid, tartaric acid, citric acid and ascorbic acid. Other preferred skin-renewal stimulating acids include mandelic acid, azelaic acid, glyceric acid, tartronic acid, gluconic acid, benzylic acid, pyruvic acid, ethyl pyruvate, 2-hydroxybutyric acid, salicylic acid, and mixtures thereof. Mineral acids in appropriate concentrations also may stimulate skin cell renewal as well as non-hydroxy acids, for example trichloracetic acid.

Accordingly, GROSS discloses a number of most diverse acids (including mineral acids and non-hydroxy acids) which can be used in the first step of the peeling method taught therein. Mandelic acid is not even among the acids which are preferably used in the peeling method of GROSS. Rather, mandelic acid and other acids (azelaic acid, glyceric acid, tartronic acid, gluconic acid, benzylic acid, pyruvic acid, ethyl pyruvate, 2-hydroxybutyric acid and salicylic acid) are mentioned only as examples of "other preferred skin-renewal stimulating acids". In line therewith, none of the compositions of Examples 1 to 3 of GROSS comprises mandelic acid.

In other words, mandelic acid clearly is not the only α-hydroxycarboxylic acid which is mentioned in GROSS and does not even belong to the group of the particularly

preferred acids (for the first step of the two-step peeling method disclosed therein). In this regard, it further is noted that even in the case of GROSS the particularly preferred acids (glycolic acid, lactic acid, malic acid, tartaric acid, citric acid and ascorbic acid) are exclusively non-aromatic acids, which is consistent with the teaching of RUBINO (which also mentions exclusively non-aromatic acids, see above).

Regarding the rejection over RUBINO in view of BHAKOO (as allegedly evidenced by HEI), Appellants submit that the Examiner's allegations are somewhat far-fetched. Even if one where to assume, *arguendo*, that one of ordinary skill in the art would be motivated to include a deodorant in the compositions of RUBINO and would for this purpose choose an antimicrobial agent in view of the teaching of BHAKOO, it is not seen that there would be an apparent reason for one of ordinary skill in the art to choose mandelic acid as the antimicrobial agent.

In particular, BHAKOO explicitly teaches in paragraphs [0006] and [0007] thereof that the antimicrobial benefit and subsequent malodor reduction obtained with typical antimicrobial agents that are used as deodorants, particularly many hours after application, "is not always excellent" and that the inventors of BHAKOO have discovered synergistic mixtures of picolinic acid and a peroxyl species or equivalent source thereof that can achieve the target of providing an excellent antimicrobial benefit and subsequent malodor reduction. BHAKOO does not appear to mention mandelic acid, i.e., not even as an antimicrobial agent which is comparable with the typical antimicrobial agents which are used as deodorants.

HEI merely teaches antimicrobial compositions which contain antimicrobially active solvents as set forth in col. 7, lines 1-45 thereof and preferably contain an (optional) additional antimicrobial agent which can be dissolved or dispersed in the antimicrobially-active solvent or in the diluting solvent (col. 10, lines 22-25). Mandelic acid is included in a laundry list of specific compounds and types of compounds of most diverse structures which may be used as additional antimicrobial agent. According to the paragraph bridging columns 10 and 11 of HEI compositions which contain "such optional additional antimicrobial agents appear to have substantially greater antimicrobial effectiveness than comparison aqueous solutions or dispersions containing the additional antimicrobial agent alone."

In other words, HEI makes it clear that if used alone, compounds such as, e.g., mandelic acid are not particularly effective as antimicrobial agents, and HEI fails to teach or suggest that mandelic acid by itself would be useful as deodorant.

It further is pointed out that although HEI discloses a large number and variety of potential uses for the antimicrobial compositions disclosed therein (see col. 11, line 58 to col. 13, line 32) the application of these compositions to human skin is not taught or suggested. The closest disclosure in this regard appears to be in col. 12, lines 28-30 of HEI where it is stated that "[t]he antimicrobial compositions of the invention can be used for treating skin diseases on animals (especially mammals)".

Appellants further point out that claims 34 and 55 both recite, *inter alia,* that in the claimed formulation the antiperspirant active ingredient, mandelic acid and water are present in ratios which result in gelling. RUBINO fails to teach or suggest that in the

compositions disclosed therein the aluminum and zirconium compounds, the hydroxycarboxylic acid and water should be present in ratios which result in gelling. On the contrary, according to, e.g., col. 3, lines 66 to col. 4, line 2 of RUBINO "[i]t is believed that the salts of hydroxyl carboxylic acids, even if insoluble in water, form complexes with the zirconium compounds and basic aluminum compounds, which complexes are soluble in water". Moreover, Example IX of RUBINO particularly relied upon by the Examiner in this regard also fails to disclose any gel but rather mentions a (clear) solution. At any rate, as pointed out above, RUBINO does not even mention mandelic acid (or any other aromatic acid).

It is not seen that the above-noted deficiency of RUBINO is cured by any of GROSS, BHAKOO and HEI, and neither does the Examiner provide any explanation in this regard.

Regarding claim 55 it additionally is noted that this claim recites concentration ranges for the antiperspirant active ingredient and mandelic acid in the formulation claimed therein. Appellants note that in this regard the Examiner relies on Example IX of RUBINO and alleges that RUBINO "teaches a formulation (after drying and reconstitution) that has approximately 17% antiperspirant active agent and approximately 2.5% α-hydroxycarboxylic acid". Page 7, second paragraph of the August 26, 2009 Final Office Action.

Appellants submit that the Examiner has not explained how the cited concentrations were calculated, wherefore Appellants are not in a position to verify this calculation. At any rate, it is pointed out that the α-hydroxycarboxylic acid used in

Example IX of RUBINO is citric acid, i.e., an aliphatic tricarboxylic acid, not mandelic acid, i.e., an araliphatic monocarboxylic acid, and the Examiner has failed to explain why one of ordinary skill in the art would (nevertheless) be prompted to replace citric acid in Example IX of RUBINO by the same amount of mandelic acid (if one were to assume, *arguendo*, that one of ordinary skill in the art would have an apparent reason to replace citric acid by mandelic acid).

Appellants further point out that claim 55 also recites that components (a) to (c) are present in ratios which result in gelling. Nothing in Example IX of RUBINO suggests that a gel is present. On the contrary, Example IX mentions a (20%) solution formed by reconstituting with water the solid material that was obtained by drying a clear solution.

b. Independent claim 49

Independent claim 49 expressly states that the antiperspirant active ingredient of the formulation recited therein is free from zirconium containing antiperspirant active ingredients and contains the recited components (a), (b) and (c) in ratios which result in gelling.

In contrast, the antiperspirant compositions of RUBINO must contain zirconium in the form of a combination (complex) of a basic aluminum compound, a zirconium compound and a hydroxycarboxylic acid (see, e.g., abstract and claims of RUBINO). Accordingly, RUBINO clearly fails to teach or suggest that in the compositions disclosed therein zirconium can be dispensed with but rather teaches away from a corresponding composition.

RUBINO also fails to teach or suggest that in the compositions of RUBINO the aluminum compound, the hydroxycarboxylic acid and water should be present in ratios which result in gelling. On the contrary, according to, e.g., col. 3, lines 66 to col. 4, line 2 of RUBINO "[i]t is believed that the salts of hydroxyl carboxylic acids, even if insoluble in water, form complexes with the zirconium compounds and basic aluminum compounds, which complexes are soluble in water". Also, Example IX of RUBINO particularly relied upon by the Examiner also fails disclose any gel but rather mentions a (clear) solution.

It is not seen that any of GROSS, BHAKOO and HEI is able to cure any of the above-noted deficiencies of RUBINO, and neither does the Examiner provide any explanation in this regard.

c. Claims which do not stand or fall together with the independent claims

Instant claims 38-40 recite various ratios of the at least one antiperspirant active ingredient and mandelic acid in the formulation of claim 34. Appellants note that in this regard the Examiner relies on Example IX of RUBINO and alleges that in this Example "the ratio by weight of antiperspirant active ingredients to α-hydroxycarboxylic acid is approximately 7:1". Page 6, fourth paragraph from bottom of the August 26, 2009 Final Office Action.

Appellants submit that the Examiner has not explained how the cited ratio was calculated, wherefore Appellants are not in a position to verify this calculation. At any rate, it is pointed out that the α-hydroxycarboxylic acid used in Example IX of RUBINO is citric acid, i.e., an aliphatic tricarboxylic acid, not mandelic acid, i.e., an araliphatic

monocarboxylic acid, and the Examiner also has failed to explain why one of ordinary skill in the art would (nevertheless) be prompted to replace citric acid in Example IX of RUBINO by the same amount of mandelic acid (if one were to assume, *arguendo*, that one of ordinary skill in the art would have an apparent reason at all to replace citric acid by mandelic acid).

Appellants further point out that independent claim 34 recites that components (a) to (c) are present in ratios which result in gelling. Nothing in Example IX of RUBINO suggests that a gel is present. On the contrary, Example IX mentions a (20%) solution formed by reconstituting with water the solid material that was obtained by drying a clear solution.

The above arguments equally apply to claim 56 (which depends from claim 55).

Instant claims 41-45 recite various concentration ranges for the at least on antiperspirant active ingredient and mandelic acid in the formulation of claim 34. Appellants note that in this regard the Examiner relies on Example IX of RUBINO and alleges that RUBINO "teaches a formulation (after drying and reconstitution) that has approximately 17% antiperspirant active agent and approximately 2.5% α-hydroxycarboxylic acid)". Page 6, third paragraph from bottom of the August 26, 2009 Final Office Action.

Appellants submit that the Examiner has not explained how the cited concentrations were calculated, wherefore Appellants are not in a position to verify this calculation. At any rate, it is pointed out that the α-hydroxycarboxylic acid used in Example IX of RUBINO is citric acid, i.e., an aliphatic tricarboxylic acid, not mandelic

acid, i.e., an araliphatic monocarboxylic acid, and the Examiner also has failed to explain why one of ordinary skill in the art would (nevertheless) be prompted to replace citric acid in Example IX of RUBINO by the same amount of mandelic acid (if one were to assume, *arguendo*, that one of ordinary skill in the art would have an apparent reason at all to replace citric acid by mandelic acid).

Appellants further point out that independent claim 34 recites that components (a) to (c) are present in ratios which result in gelling. Nothing in Example IX of RUBINO suggests that a gel is present. On the contrary, Example IX mentions a (20%) solution formed by reconstituting with water the solid material that was obtained by drying a clear solution.

Claim 47 (which depends from claim 34) and claim 57 (which depends from claim 56, which in turn depends from claim 55) both recite that the formulation recited in the base claim has a defined yield point. Claim 48 recites that the formulation of claim 34 is present as a hydrogel. Appellants note that in this regard the Examiner alleges that "the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component", and essentially appears to argue that in view thereof the properties recited in claims 47, 48 and 57 are allegedly inherent in the compositions of RUBINO. See page 7, last paragraph of the August 26, 2009 Final Office Action.

Appellants submit that it is not seen that "the prior art appears to contain the exact same ingredients", let alone in ratios which result in the formation of a gel. In this regard, it is pointed out that the instant independent claims make it clear that not each and every

ratio of components (a), (b) and (c) results in the formation of a gel (otherwise the passage "(a), (b) and (c) being present in ratios which result in gelling" recited in these claims would be redundant).

Claim 52 recites that the (zirconium-free) antiperspirant formulation of claim 49 comprises mandelic acid as the at least one α-hydroxycarboxylic acid.

Appellants submit that RUBINO does not even mention mandelic acid. Further, for at least all of the reasons which are set forth above in connection with the rejection of independent claims 34 and 55 (incorporated herein), none of GROSS, BHAKOO and HEI is able to provide an apparent reason for one of ordinary skill in the art to replace the (aliphatic) hydroxycarboxylic acids mentioned in RUBINO by mandelic acid.

To sum up, for at least all of the foregoing reasons, the Examiner has failed to establish a *prima facie* case of obviousness of the subject matter of any of claims 34-49, 52 and 55-57 over RUBINO in view of GROSS or BHAKOO, which warrants a reversal of the instant rejection.

C. Claims 34-57 Are Not Properly Rejected Under 35 U.S.C. 103(a) As Being Unpatentable Over GUSKEY

1. Summary of Rejection

The rejection essentially alleges that GUSKEY teaches a topical pharmaceutical composition comprising at least one active agent, a gelling agent, and an anhydrous solvent and that among the active agents, aluminum and aluminum-zirconium chlorohydrate and mandelic acid are mentioned. The rejection also notes that while

GUSKEY teaches that an anhydrous solvent is used, GUSKEY teaches that the anhydrous solvent may contain up to 5 % of water.

2. Traverse

a. GUSKEY fails to provide an apparent reason for the employment of water (in an amount which results in gelling)

Appellants point out that all of the instant independent claims recite, *inter alia*, that antiperspirant active agent, α-hydroxycarboxylic acid (mandelic acid) and water are present in ratios which result in gelling.

In contrast, GUSKEY fails to teach or suggest that water is an essential component of the pharmaceutical compositions disclosed therein, let alone that water needs to be present in a concentration - relative to the concentrations of antiperspirant active agent and α-hydroxycarboxylic acid - which results in the formation of a gel. In this regard, it further is pointed out that even if one were to assume, *arguendo*, that the concentration of water in the compositions of GUSKEY can be unlimited, there would be no apparent reason for one of ordinary skill in the art to adjust the amount of water with respect to antiperspirant active agent and α-hydroxycarboxylic acid so that the ratio of these three components results in gelling because the compositions of GUSKEY already contain a gelling agent (as acknowledged by the Examiner).

At any rate, GUSKEY teaches that water not only is not an essential component of the pharmaceutical compositions disclosed therein but even makes is clear that the presence of water in these compositions is undesirable and should be avoided to the greatest possible extent.

For example, component C of the compositions of GUSKEY (in addition to at least one pharmaceutical active A and a specific type of gelling agent B) is an anhydrous liquid carrier. See, e.g., independent claims 1 and 19 of GUSKEY. In this regard, GUSKEY states in col. 10, lines 21-35 thereof (emphasis added):

> The anhydrous liquid carrier preferably comprises one or more anhydrous liquids suitable for topical application to human skin, which carrier or combination of liquid carriers are liquid under ambient conditions. The term "anhydrous" as used herein means that the pharmaceutical gel compositions of the present invention, and the essential or optional components thereof other than the pharmaceutically acceptable actives, are substantially free of added or free water. From a formulation standpoint, this means that the pharmaceutical gel compositions of the present invention preferably contain less than about 5%, preferably less than about 3%, more preferably less than about 1%, most preferably zero percent, by weight of free or added water, other than the water of hydration typically associated with the pharmaceutically acceptable actives prior to formulation.

Accordingly, even if GUSKEY indicates that the presence of (unintentionally present) small amounts of water in the compositions disclosed therein can be tolerated, GUSKEY nevertheless provides a clear teaching that water is most preferably completely absent from these compositions. It is not seen that this prompts one of ordinary skill in the art to intentionally employ water in any amount, let alone to employ water in an amount which results in a ratio with respect to antiperspirant active agent and α-hydroxycarboxylic acid that results in gelling (as pointed out above, the compositions of GUSKEY must contain a (specific) gelling agent, anyway).

Appellants note that in the Continuation Sheet of the November 4, 2009 Advisory Action the Examiner alleges, *inter alia*, that Appellants acknowledge that GUSKEY contains a gelling agent which is not excluded by the "comprising" language in the instant claims, "which means that any amount of water would be sufficient to 'result in gelling'".

Appellants submit that the Examiner clearly has misconstrued the present claims in this regard. Independent claims 34, 49 and 55 unambiguously recite that water is present in a ratio with respect to (a) at least one antiperspirant active ingredient and (b) α-hydroxycarboxylic acid (mandelic acid) that results in gelling, i.e., these claims recite not merely that (i) the formulation comprises components (a), (b) and (c) and (independently) (ii) the formulation is present in the form of a gel.

b. GUSKEY fails to teach or suggest the simultaneous use of antiperspirant active ingredient and α-hydroxycarboxylic acid (and water)

Appellants further point out that GUSKEY mentions aluminum or aluminum-zirconium chlorohydrate and mandelic acid only as two examples of the many types of active agents which may be present in the compositions disclosed therein (i.e., antiseptic or antibacterial actives, antifungal agents, hormones, exfoliating agents, topical analgesics, sunscreen actives, antidandruff agents, antioxidants and vitamins, to name but a few).

In addition, mandelic acid is mentioned in GUSKEY as an example of an exfoliating agent (consistent with the disclosure of GROSS) whereas aluminum and aluminum-zirconium chlorohydrates are mentioned in GUSKEY as examples of antiperspirant actives which may be present in the compositions taught therein (see col. 5, lines 34-50 and col. 7, lines 40-47 of GUSKEY).

It is not seen that there is any relationship between an exfoliating agent and an antiperspirant active, let alone a relationship which would make the simultaneous use thereof appear expedient and desirable. In other words, there apparently is no benefit in

having an exfoliating agent and an antiperspirant active present in a cosmetic composition at the same time. Accordingly, there is no apparent reason for one of ordinary skill in the art to provide a composition in accordance with the teaching of GUSKEY that comprises (i) an exfoliating agent and in particular, an α-hydroxycarboxylic acid such as, e.g., mandelic acid, (ii) an antiperspirant active (and (iii) water), let alone in relative ratios which result in a gelling of the composition.

Appellants note that in the Continuation Sheet of the November 4, 2009 Advisory Action the Examiner alleges, *inter alia*, that "exfoliating and antiperspirant agents could be applied to the same area of skin (antiperspirants, though usually applied to the armpit, do not find there sole use there) and combining agents for skin care in a composition also for skin care would have been prima facie obvious".

In this regard, it is submitted that even if one were to agree with the Examiner, *arguendo*, that "exfoliating and antiperspirant agents could be applied to the same area of skin", the question here is whether one of ordinary skill in the art would consider it desirable to apply exfoliating and antiperspirant agents to the same area of the skin at the same time. Moreover, the Examiner has failed to identify those alleged areas of the skin, different from the skin of the armpits (and in particular areas of the skin which could benefit from an exfoliating treatment), onto which antiperspirants are usually applied. Further, Appellants also fail to see that the purpose of antiperspirants is skin care.

c. GUSKEY fails to teach or suggest that the compositions taught therein are transparent

All of the instant independent claims recite, *inter alia*, that the claimed formulation is transparent. The only comment that is offered by the Examiner in this

regard is that "compositions of identical chemical composition must have identical properties. In addition, Guskey et al. teach that the invention leaves a reduced visible residue (column 2, lines 19-24)". Page 10, next-to-last paragraph of the August 26, 2010 Final Office Action.

Appellants fail to see that the compositions of GUSKEY and the claimed formulations have an identical chemical composition, let alone that in the compositions of GUSKEY the ratios of antiperspirant active ingredient, α-hydroxycarboxylic acid (mandelic acid) and water result in gelling.

It also is not seen that because the compositions of GUSKEY leave a reduced visible residue they must necessarily be transparent, and neither does the Examiner offer any explanation in this regard.

d. Additional reasons why GUSKEY fails to render obvious specific claims

Instant claims 38-40 recite various ratios of the at least one antiperspirant active ingredient and mandelic acid in the formulation of claim 34. Appellants note that in this regard the Examiner merely relies on the fact that GUSKEY mentions that the active agents in the composition taught therein are present in a safe and effective amount, wherefore one of ordinary skill in the art would allegedly arrive at the ratios recited in claims 38-40 empirically. Paragraph bridging pages 10 and 11 of the August 26, 2009 Final Office Action.

Appellants fail to see that the use of safe and effective amounts of antiperspirant active ingredient and mandelic acid (if used together) in a composition according to GUSKEY would automatically result in a ratio within the ranges recited in claims 38-40.

It further has to be taken into account here that the ratio of these components and water together additionally have to result in gelling. GUSKEY is completely silent in this regard.

The above arguments equally apply to claim 56 (which depends from claim 55).

Instant claims 41-45 recite various concentration ranges for the at least on antiperspirant active ingredient and mandelic acid in the formulation of claim 34. Appellants note that in this regard the Examiner merely relies on the fact that GUSKEY mentions that the active agents in the composition taught therein are present in a safe and effective amount, wherefore one of ordinary skill in the art would allegedly arrive at the concentrations recited in claims 41-45 empirically. Paragraph bridging pages 10 and 11 of the August 26, 2009 Final Office Action.

Appellants fail to see that the use of safe and effective amounts of antiperspirant active ingredient and mandelic acid (if used together) in a composition according to GUSKEY would automatically result in concentrations within the ranges recited in claims 41-45. It further has to be taken into account here that the ratio of these components and water together additionally would have to result in gelling. GUSKEY is completely silent in this regard.

Claim 47 (which depends from claim 34) and claim 57 (which depends from claim 56, which in turn depends from claim 55) both recite that the formulation recited in the base claim has a defined yield point. Claim 48 recites that the formulation of claim 34 is present as a hydrogel. Appellants note that in this regard the Examiner alleges that "the

prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component", and essentially appears to argue that in view thereof the properties recited in claims 47, 48 and 57 are allegedly inherent in the compositions of GUSKEY. See page 11, third paragraph of the August 26, 2009 Final Office Action.

Appellants submit that it is not seen that "the prior art appears to contain the exact same ingredients", let alone in ratios which result in the formation of a gel. In this regard, it is pointed out that the instant independent claims make it clear that not each and every ratio of components (a), (b) and (c) results in the formation of a gel (otherwise the passage "(a), (b) and (c) being present in ratios which result in gelling" recited in these claims would be redundant).

Claim 49 recites, *inter alia*, that the antiperspirant formulation claimed therein is free from zirconium containing antiperspirant active ingredients.

GUSKEY neither teaches or suggests that antiperspirant containing compositions should be free of zirconium. On the contrary, several zirconium compounds are expressly mentioned in col. 7, lines 30-47 of GUSKEY as examples of antiperspirant actives which can be used in the compositions taught therein.

To sum up, for at least all of the foregoing reasons, the Examiner has failed to establish a *prima facie* case of obviousness of the subject matter of any of claims 34-57 over GUSKEY, which warrants a reversal of the instant rejection.

VIII. CONCLUSION

Appellants respectfully submit that for at least all of the foregoing reasons, the Examiner has failed to establish a *prima facie* case of obviousness of any of claims 34-57 over GUSKEY or a combination of RUBINO with any one of GROSS and BHAKOO. The Board is, therefore, respectfully requested to reverse the Final Rejection, and to allow the application to issue in its present form.

Respectfully submitted,
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CLAIMS APPENDIX

34. A cosmetic or dermatological formulation, wherein the formulation is transparent and comprises (a) at least one antiperspirant active ingredient, (b) mandelic acid and (c) water, (a), (b) and (c) being present in ratios which result in gelling.

35. The formulation of claim 34, wherein (a) comprises at least one aluminum salt.

36. The formulation of claim 35, wherein (a) comprises aluminum chlorohydrate.

37. The formulation of claim 34, wherein (a) comprises at least one aluminum zirconium salt.

38. The formulation of claim 34, wherein a ratio (a) : (b) is from 15 : 1 to 1 : 1.

39. The formulation of claim 38, wherein the ratio is from 12 : 1 to 2 : 1.

40. The formulation of claim 38, wherein the ratio is from 10 : 1 to 2.5 : 1.

41. The formulation of claim 34, wherein the formulation comprises (a) in an amount of from 1% to 35% by weight, based on a total weight of the formulation.

42. The formulation of claim 41, wherein the formulation comprises (a) in an amount of from 1% to 25% by weight.

43. The formulation of claim 41, wherein the formulation comprises (a) in an amount of from 1% to 20% by weight.

44. The formulation of claim 34, wherein the formulation comprises (b) in an amount of from 0.1% to 10% by weight, based on a total weight of the formulation.

45. The formulation of claim 44, wherein the formulation comprises (b) in an amount of from 0.1% to 8% by weight.

46. The formulation of claim 34, wherein the formulation further comprises a deodorant active ingredient.

47. The formulation of claim 34, wherein the formulation has a defined yield point.

48. The formulation of claim 34, wherein the formulation is present as a hydrogel.

49. A cosmetic or dermatological antiperspirant formulation, wherein the formulation is free from zirconium containing antiperspirant active ingredients and transparent and comprises (a) an antiperspirant active ingredient which comprises one or more aluminum salts, (b) at least one α-hydroxycarboxylic acid and (c) water, (a), (b) and (c) being present in ratios which result in gelling.

50. The formulation of claim 49, wherein (a) comprises aluminum chlorohydrate.

51. The formulation of claim 49, wherein (a) consists of aluminum chlorohydrate.

52. The formulation of claim 49, wherein (b) comprises mandelic acid.

53. The formulation of claim 49, wherein the formulation comprises (a) in an amount of from 1% to 25% by weight and (b) in an amount of from 0.1% to 10% by weight, each based on a total weight of the formulation.

54. The formulation of claim 49, wherein a ratio (a) : (b) is from 10 : 1 to 2.5 : 1.

55. A cosmetic or dermatological antiperspirant formulation, wherein the formulation is transparent and suitable for application to human skin and comprises (a) from 1% to 20% by weight of an antiperspirant active ingredient which comprises one or both of an

aluminum salt and an aluminum zirconium salt, (b) from 0.1% to 8% by weight of mandelic acid and (c) water, (a), (b) and (c) being present in ratios which result in gelling.

56. The formulation of claim 55, wherein a ratio (a) : (b) is from 10 : 1 to 2.5 : 1.

57. The formulation of claim 56, wherein the formulation has a defined yield point.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.